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REMARKS

All of pending claims 1, 3, 26-27, 33-40, and 42-45 stand rejected. Claims 2, 4-25, 28-32, 41, and 46-65 were withdrawn from consideration. Claims 19, 35, and 55 are canceled herewith. Claims 1, 20, 36, and 56 are amended herewith. Thus, upon entry of this amendment and accompanying remarks, claims 1, 3, 26-27, 33-34, 36-40, and 42-45 remain pending in the present application, with claims 2, 4-18, 20-25, 28-32, 41, 46-54, and 56-65 being withdrawn in the absence of rejoinder as requested herein.

Claim Amendments

Claim 1 has been amended. Support for the amendments to claim 1 can be found throughout the originally filed specification, including the compositions exemplified therein. The recited weight percentage of the recited strontium cation has been amended such that it is consistent with the language in related U.S. Patent No. 5,804,203. In addition, claim 1 has been amended to recite one embodiment of the invention where the formulation comprises a separate “non-strontium active ingredient” from the salt of an aqueous-soluble divalent strontium cation as discussed on, for example, page 18, lines 11-14, page 24, lines 15-19, and page 39, line 24, to page 40, line 8, of the present application. Finally, claim 1 has been amended to recite one embodiment of the invention, where the topical formulation is packaged with instructions directing administration of the formulation to “external” skin of an animal subject. Such formulations are distinguished from oral compositions as described on, for example, page 43, lines 10-20, of the present application. It is believed that no new matter is introduced by these amendments.

The 35 U.S.C. §102 Rejection

Claims 1, 3, 26-27, 33-36, and 42-43 are newly rejected under 35 U.S.C. §102(b) as allegedly being anticipated by European Patent Document No. EP 0 346 957 (“Bristow”). This rejection is respectfully traversed.

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Bristow relates to an oral composition containing an agent for desensitizing teeth, wherein the amount of the source of potassium or strontium ions used therein is stated to be generally about 1% to about 20%, usually to about 10%, for example from 2% to 8%, more preferably 3-6% by weight of the oral composition. In conjunction with its purpose of being an oral composition, the compositions of Bristow also require a particulate abrasive material, which is hydroxyapatite, as a tooth cleaning and polishing agent (*i.e.*, the active ingredient of those compositions).

Claim 1 has been amended to recite that the topical formulations therein are packaged with instructions directing their administration to the external skin of an animal subject. While Bristow does not teach compositions stated to be useful for reducing any kind of skin irritation (but rather tooth sensitivity), Bristow undoubtedly does not teach or suggest compositions for administration to external skin as recited in amended claim 1. As noted on page 15 of the present application, beginning on line 9, while potassium and strontium salts have been employed in dentrifices for reduction of tooth sensitivity, the reduction in tooth sensitivity generally was only after two to six weeks of continuous use. In contrast to that of teeth, the human skin presents a sensory and structural environment that is much more complicated. See page 17, lines 7-20, of the present application.

Claims 3, 26-27, 33-36, and 42-43 ultimately depend from claim 1. Thus, as Bristow does not teach or suggest each and every element of the rejected claims, withdrawal of this rejection is respectfully requested. Applicants also note that claim 35 is canceled with this amendment.

The 35 U.S.C. §103 Rejections

The First Rejection

Claim 1 stands rejected under the 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,943,432 to Biener. The rejection is respectfully traversed for the reasons set forth in response to the previous Office Action.

In reply to Applicants' arguments made in response to the May 27, 2003, Office Action, the Patent Office admits that Biener "lacks an exemplification of the percent weight of strontium." Nevertheless, the Patent Office asserts that the amount of aqueous-

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soluble divalent strontium cation recited in rejected claim 1 – 0.5 to 10% by weight of the entire formulation (including the weight of a suitable topical formulation vehicle, which Biener teaches can be up to 1,000 grams water) – would have “been obvious to one of ordinary skill in the art [because] where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233.”

On page 8 of the present Office Action, the Examiner acknowledges that the amount of strontium cation in the compositions of Biener “is minor in relation to the amount of aqueous-soluble divalent strontium cation in the present invention.” Thus, it appears that the Patent Office has recognized that the claimed range is not within, but outside of, the range of strontium cation taught by Biener. Accordingly, rejected claim 1 is not merely an optimum or workable range of more general teachings. Rather, claim 1 sets forth a unique composition not taught or suggested by Biener. Thus, the Examiner’s reliance on *In re Aller* is misplaced in that Biener’s teachings do not encompass the claimed amount of strontium cation in any respect, but rather teach away from the claimed amount of this specific feature of the invention. For example, see the tables set forth by Biener at column 2, lines 26-36, column 3, lines 1-12 and 46-52, and column 4, lines 30-49. Therefore, Biener does not teach or suggest each and every element of the rejected claim 1.

In addition, claim 1 has now been amended to specify that the formulation comprises “a non-strontium active ingredient” and “a salt comprising aqueous-soluble divalent strontium cation.” As noted on page 24, lines 15-19, this embodiment of the invention beneficially overcomes several difficult problems inherent in incorporating aqueous-soluble strontium salts into aesthetic and functionally active topical products (*i.e.*, products that retain their cosmetic, therapeutic, or other functional characteristics). Such formulations of the invention, as recited in amended claim 1, not only retain their other cosmetic, therapeutic, or other functional characteristics, but they also facilitate reduced skin irritation due to the presence of the salt comprising aqueous-soluble divalent strontium cation therein. While the salt comprising aqueous-soluble divalent strontium cation is not necessary to fulfill the cosmetic, therapeutic, or other primary functional

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characteristic of the formulation, its presence imparts a beneficial reduction in skin irritation upon administration of the formulation to the external skin of an animal subject.

Biener does not teach or suggest formulations with these two distinct components. In contrast, Biener describes a diverse salt mixture for the treatment of psoriasis. Strontium cations are one of many cations recited as being used in combination as an active ingredient to assimilate Dead Sea water salt treatments for the treatment of psoriasis. The salt mixtures are the active ingredient taught by Biener in that the salt mixture itself is stated to provide the treatment of psoriasis. Thus, Biener does not teach a non-strontium active ingredient or a salt comprising aqueous-soluble divalent strontium cation, let alone the unique combination of those two components, in a topical formulation.

For the foregoing reasons, withdrawal of this rejection is respectfully requested.

The Second Rejection

Claims 3, 26, 33-38, and 42 stand rejected under the 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,943,432 to Biener in view of U.S. Patent No. 4,477,439 to D'Alelio. The rejection is respectfully traversed.

Each and every element of claim 1 is not taught or suggested by Biener as noted above. Claims 3, 26, 33-38, and 42 ultimately depend from claim 1. Thus, Biener also does not teach each and every element of rejected claims 3, 26, 33-38, and 42. The Patent Office's application of D'Alelio in setting forth this rejection of alleged obviousness does not overcome the noted deficiencies of Biener.

Applicants again note that one of ordinary skill in the art would not be motivated to make the asserted combination of Biener and D'Alelio, nor would one of ordinary skill in the art expect such a combination to be successful. On page 8 of the current Office Action, the Examiner's response to Applicants' previous arguments that D'Alelio does not teach the use of aqueous-soluble strontium salts and that D'Alelio teaches away from addition of an irritant ingredient is that the reason for combination of D'Alelio with Biener was not to address those items, but merely "to show that lotion is an obvious vehicle form of a topical composition." However, the Examiner has not provided any

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evidence that such a combination would have a reasonable expectation of success. Indeed, in view of the disparate teachings in regards to exclusion versus inclusion of irritant ingredients and the types of strontium salts used (*i.e.*, aqueous-soluble versus insoluble), Applicants believe that one of ordinary skill in the art would not expect such a combination to succeed.

Thus, the applied combination of Biener and D'Alelio does not teach or suggest each and every element of the rejected claims. Withdrawal of this rejection is requested. Applicants also note that claim 35 is canceled with this amendment.

The Third Rejection

Claims 39-40 stand rejected under the 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,943,432 to Biener in view of U.S. Patent No. 4,477,439 to D'Alelio, and further in view of U.S. Patent Publication No. 2001/0016604 to Yu et al. The rejection is respectfully traversed.

Each and every element of claim 1 is not taught or suggested by Biener as noted above. Claims 39-40 ultimately depend from claim 1. Thus, Biener also does not teach each and every element of rejected claims 39-40. The Patent Office's application of D'Alelio and Yu et al. in setting forth this rejection of alleged obviousness does not overcome the noted deficiencies of Biener.

Further, rejected claims 39 and 40 directly depend from claim 38. As discussed previously, D'Alelio teaches away from claim 38, which recites topical formulations further comprising an irritant ingredient. Yu et al. is no more than background documentation describing topical applications for treatment of dandruff and acne. Yu et al. do not even teach or suggest strontium-containing compositions. Therefore, the combination of Yu et al. does not overcome the deficiencies of Biener and/or D'Alelio in that regard.

In conclusion, the applied combination of Biener, D'Alelio, and Yu et al. does not teach or suggest each and every element of the rejected claims. Withdrawal of this rejection is requested. Applicants also note that claim 35 is canceled in this amendment.

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The Fourth Rejection

Claims 27 and 42-45 stand rejected under the 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,943,432 to Biener in view of U.S. Patent No. 4,477,439 to D'Alelio, and further in view of U.S. Patent No. 5,665,364 to McAtee. The rejection is respectfully traversed.

Each and every element of claim 1 is not taught or suggested by Biener as noted above. Claims 27 and 42-45 ultimately depend from claim 1. Thus, Biener also does not teach each and every element of rejected claims 27 and 42-45. The Patent Office's application of D'Alelio and McAtee in setting forth this rejection of alleged obviousness does not overcome the noted deficiencies of Biener. For example, McAtee does not teach or suggest strontium-containing compositions. Therefore, McAtee does not overcome the deficiencies of Biener and/or D'Alelio as noted above.

In conclusion, the applied combination of Biener, D'Alelio, and McAtee does not teach or suggest each and every element of the rejected claims. Withdrawal of this rejection is requested.

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Conclusion

In view of the foregoing, allowance of all pending claims is respectfully requested. Further, due to their ultimate dependency from pending claim 1, rejoinder and allowance of all withdrawn claims is also requested. If deemed useful in order to further prosecution of this application to allowance, the Examiner is invited to contact the undersigned by telephone, e-mail, facsimile, or written communication.

Respectfully Submitted,

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